MAY - 4 2005

K 050838

Section E 510(k) SUMMARY

Submitted by: Jensen Industries
50 Stillman Road
North Haven CT 06473
(203) 239-2090 phone
(203) 234-7630 fax
Contact: Gary Phelps

Date Prepared: March 3, 2005
Device Name: The LF-P Ceramic System
Common Name: Dental Porcelain
Classification: Class II
Product Code: EIH

Predicate Devices: Ceramco Finesse All Ceramic (K971869)
Willi Geller Creation & LF (K002904)

Device Description

The LF-P Ceramic System is a ceramic material formed into pellets intended for pressing into full contour restorations (crowns, onlays, inlays and veneers) and substructures as well as pressing to conventional precious and non-precious metal substructures. The system also includes low fusion ceramics suitable for layering or stain / glaze finishing. Data has been presented to demonstrate that the mechanical properties, chemical qualities, and the indications for use make the ***LF-P Ceramic System*** substantially equivalent to the predicate devices ***Ceramco Finesse All Ceramic and Willi Geller Creation & LF***. The safety and effectiveness of the ***LF-P Ceramic System***, being determined by the chemical qualities, cytotoxicity test results and mechanical properties, is therefore equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 4 2005

Mr. Gary Phelps
Quality Assurance Manager
Jensen Industries, Incorporated
50 Stillman Road
North Haven, Connecticut 06473

Re: K050838
Trade/Device Name: The LF-P Ceramic System
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: March 30, 2005
Received: April 06, 2005

Dear Mr. Phelps:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

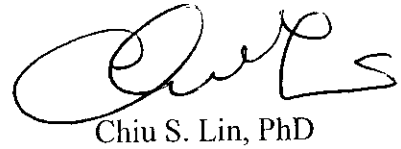
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Indications for Use

510(k) Number (if known): K050838

Device Name: ***The LF-P Ceramic System***

Indications for Use: ***the LF-P Ceramic System*** is a ceramic material formed into pellets intended for pressing into full contour restorations (crowns, onlays, inlays and veneers) and substructures as well as pressing to conventional precious and non-precious metal substructures. The system also includes low fusion ceramics suitable for layering or stain / glaze finishing.

Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Mulvey for N SR

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K050838